OPEN MINUTES Missouri Board of Pharmacy Telephone Conference Call May 11, 2016

The Missouri Board of Pharmacy met via telephone conference call in open session during the times and dates stated in the following minutes. The meeting was called to order by President Christina Lindsay at 3:08 p.m. on May 11, 2016. Each item in the minutes is listed in the order discussed.

Board Members Present

Christina Lindsay, President Christian Tadrus, PharmD, Vice-President Barbara Bilek, PharmD, Member Douglas Lang, R.Ph., Member Anita Parran, Public Member

Staff Present

Kimberly Grinston, Executive Director Tom Gle**n**ski, Chief Inspector Katie DeBold, Inspector Jennifer Luebbert, Administrative Coordinator

Other Attendees

Curtis Thompson, Legal Counsel

Staff/Board Members Absent

Pamela Marshall, R.Ph.

#C1 Applications for Intern Training Special Site/Non-Pharmacist Preceptor

- CVS Pharmacy District Office
- CVS Regional Business Office
- Jesse Brown VA Medical Center
- Sharp Rees-Stealy Pharmacy Benefits Administration
- Veterans Affairs Medical Center Jefferson Barracks (VA-JB)
- Walgreens District Office
- Walmart Multisite Management

DISCUSSION: Tom Glenski recommended approval of all special sites/non-pharmacist preceptors. Christian Tadrus asked for additional information on the training that will be provided at the Walmart special site. A motion was made by Christian Tadrus, seconded by Douglas Lang, to approve all Intern Training Special Site/Non-Pharmacist Applications for 500 hours with the exception of the Walmart Multisite

^{*} Board member Barbara Bilek joined the meeting at 3:18 p.m.

Management site. It was further moved that staff request additional information on the proposed Walmart training program. Motion passed 3:0:0:2 with roll call vote as follows:

Barbara Bilek – absent Douglas Lang- yes Pamela Marshall – absent Anita Parran – yes Christian Tadrus – yes

#C2 STLCOP Site/Preceptor List

- STLCOP Site Listing
- STLCOP Preceptor Listing

DISCUSSION: Tom Glenski recommended approval of the school lists as presented. A motion was made by Christian Tadrus, seconded by Anita Parran, to approve the site/preceptor lists as recommended. Motion passed 3:0:0:2 with roll call vote as follows:

Barbara Bilek – absent Douglas Lang- yes Pamela Marshall – absent Anita Parran – yes Christian Tadrus – yes

#D1 New FDA Guidance on 503A and 503B

- Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act (draft)
- Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic Act (draft)
- Facility Definition Under Section 503B of the Federal, Drug, and Cosmetic Act (draft)

DISCUSSION: Kimberly Grinston reported the agenda materials were provided for informational purposes. Christian Tadrus expressed concerns that the FDA has not provided clear direction and asked how the guidance documents would affect pharmacists operating under protocol. Board consensus to add this topic to the July strategic planning meeting.

#D2 2016 Legislative Update

- SB 875(Truly agreed and finally passed): http://www.senate.mo.gov/16info/pdf-bill/perf/SB875.pdf
- HB 2007 (budget bill)-no documents
- SB 579: http://www.senate.mo.gov/16info/pdf-bill/perf/SB579.pdf

DISCUSSION: Kimberly Grinston reported SB 875 has passed along with the Board's proposed language requiring reporting of out-of-state discipline. Other pharmacy related proposals are still pending, including, consolidation of refills, MAC pricing and telehealth/telemedicine. Ms. Grinston reported the PMP bill has stalled in the Senate and indicated she does not believe it will pass this year. Christina Lindsay asked if the PMP bill would allow practitioners/pharmacies access to the data; Kimberly Grinston reported one of the proposals would only grant BNDD data access.

BARBARA BILEK JOINED THE CONFERENCE CALL AT 3:18 P.M.

#D3 Sterile Compounding Emergency/Amended rule

#D5A Revised Sterile Compounding Rule

- Email from Grinston
- SC Emergency Rule (draft)
- SC Amended Rule (draft)

DISCUSSION: (These agenda items were discussed together). Kimberly Grinston reported the subcommittee met several times and also met with various industry stakeholders to develop the draft rule. Ms. Grinston indicated USP Chapter 797 revisions may not be complete until 2017/2018 although an exact date is unknown. Board discussion was held. Christian Tadrus inquired about the fiscal note and asked if costs were estimated over the life of the rule. Mr. Tadrus noted the higher fiscal note is likely to garner additional review/comments. Douglas Lang suggested sterile gloves should be required for all risk levels and noted that 75% of responders to the Board's previous sterile compounding survey indicated using sterile gloves already. Christina Lindsay asked inspector Katie DeBold about what she is seeing in the field; Katie DeBold replied approximately 50% of licensees are using sterile gloves. Christian Tadrus suggested revisiting the sterile gloves requirement after USP Chapter 797 is revised. Additional Board discussion was held on requiring sterile alcohol. Douglas Lang and Barbara Bilek indicated the rule should allow for sterile alcohol or use of an equivalent or superior agent. Board consensus to revise the emergency/amended rule as reflected in Attachment A. A motion was made by Christian Tadrus, seconded by Barbara Bilek, to approve the proposed changes as reflected in Attachment A and to bring the draft rules back to the Board for final approval before filing. Motion passed 4:0:0:1 with roll call vote as follows:

Barbara Bilek- yes

Douglas Lang- yes Pamela Marshall – absent

Anita Parran – yes

Christian Tadrus - yes

#D6A NABP Annual Meeting

DISCUSSION: Kimberly Grinston reported she asked legal counsel for advice related to Missouri's Sunshine Law that should be discussed in closed.

#D4 Update on Board of Healing Arts discussion on telehealth/telemedicine

DISCUSSION: Kimberly Grinston reported she will provide additional updates in June.

THE FOLLOWING ITEMS WERE REVIEWED IN SECTION E, WHICH REQUIRED NO ACTION OR DISCUSSION.

#E1 Approval of Hospital Advisory Committee Group Minutes

- November 6, 2015 Hospital Advisory Committee Minutes
- December 14, 2015 Hospital Advisory Committee Minutes

MOTION TO CLOSE 4:40 P.M.

At 4:40 p.m., Barbara Bilek made a motion, seconded by Anita Parran, that the Board go into closed session and that all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting be closed under Section 620.021(1), (5), (7), and (14), RSMo, and under Section 324:001.8, RSMo. Motion passed 4:0:0:1 with roll call vote as follows:

Barbara Bilek- yes

Douglas Lang- yes Pamela Marshall - absent

Anita Parran – yes

Christian Tadrus - ves

By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 5:58 p.m.

MOTION TO ADJOURN

At approximately 5:59 p.m., upon motion made by Barbara Bilek, seconded by Christian Tadrus, the May 11, 2016, open session conference call meeting was adjourned. Motion passed 3:0:0:2 with roll call vote as follows:

Barbara Bilek- yes

Douglas Lang- yes Pamela Marshall - absent

KIMBERLY/A. GRINSTON

EXECUTIVE DIRECTOR

Date Approved: 10/26/2016